K022540

OCT 2 4 2002

510(K) Summary

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Submitter:

Mark Rosoff, President
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Contact: Mark Rosoff
Date of Summary: 7-31-2002

Name of Device: Holter Recorder Cardio ID+ RZ153+
Common Name: RZ153+
Classification Name: Recorder, Magnetic Tape, Medical

Substantial Equivalence claimed to legally marketed device:
Holter Recorder DR180 II (K001288)

Description of Device:

The basic operation of the Holter Recorder RZ153+ is to collect and store multiple channels of ECG data along with impedance measurements. The Holter scanner software reads this data and it can be printed out in tabular form or graphical form.

This recorder is not capable of any diagnosis nor can it provide any interpretation of the data. It can only display and store the data. The Holter for Windows software reads this data and provides ability to the user to review, edit and print the data collected.

Intended Use of Device

The intended use of the Holter Recorder Rz153+/ Cardio ID+ is to perform ambulatory ECG and impedance recording, on the order of a physician, on those patients who may benefit from such a recording, including, but not limited to, those with complaints of palpitations, syncope, chest pain, shortness of breath, or those that need to be monitored to judge their current cardiac functionality such as patients who have recently received pacemakers. The data obtained at recording is not analyzed at the time of the recording.

The data is intended to be downloaded to an analysis software package after the recording is completed.

Comparison of Technology Characteristics to the Predicate Device

Specification	**RZ153+ New Device**	**DR180 II Predicate Device**
Online data monitoring & alarm	**No**	**No**
Recorded ECG channels	Multiple	Multiple
Sample rate & resolution	1024 S/s & 12 bits	180/360/720 S/s & 12 bits
Bit resolution	1,465 µV / LSB	6.25 µV / LSB
Max. input voltage range	± 6, ± 3 or ± 1.5 mV	± 1.5 mV
Amplification factors	1/2, 1 or 2	1
Analogue bandwidth	0.05 Hz to 75 Hz	0.05 Hz to 20 Hz
Pacemaker detection & reporting	Yes	Yes
Open-Lead detection & reporting	Yes	Yes
Impedance Measurement	Yes	Yes
Preferred recording period	24h, 48h or user defined	24 h or continuously
Storage capacity	Up to 512 MB	Up to 512MB
Recording capacity	Up to 120 hours / 5 days	Up to 50 hours
Memory type	CompactFlash™ Memory Card Type II or Type I	CompactFlash™ Memory Card
Data transfer method	Via removable Memory Card	Via removable Memory Card
Memory Card data format	Standard file system	Standard file system
Data overwrite protection	Yes	Yes
Internal memory card management	Reformat, erase cards	Reformat, erase cards
Liquid crystal display (LCD)	Yes	Yes
Keyboard	protected touch keys	protected touch keys
Number of keys	5	13
Patient leakage current	< 1 µA	0 mA
Size	108 * 79 * 22 mm 4 1/4 * 3 1/8 * 7/8"	125 * 70 * 25 mm 4 7/8" * 2 3/4" * 1"
Weight	145 g /5.12 oz	195 g/6.88oz
Belt clip / Carrier pouch	Carrier bag (Pouch)	Carrier bag (Pouch)
Battery	1 or 2 * 1.5 V AA	2 * 1.5 V AA
Accepts rechargeable batteries	Yes, 1 or 2 * 1.2 V AA	Yes, 2 * 1.5 V AA

Specification	RZ153+ New Device	DR180 II Predicate Device
Battery check prior recording	Yes	Yes
Internal Clock w. Battery	Yes	Yes
Clock setting functionality	Yes	Yes
External patient cable	Yes	Yes
Record identification procedure	Yes	Yes
ECG channel preview	Yes	Yes
Signal quality check prior recording	Yes	Yes
Multi-language support	Yes	Yes
Autostart when ready	Yes	Yes
Autostop on problems / data overwrite protection	Yes	Yes

Conclusion

The Holter recorder RZ153+ and the Holter recorder DR180 II are both used in clinical applications to collect ambulatory electrocardiographic recordings that can be downloaded to the Holter for Windows® scanner software.

The RZ153+ conforms to Good Manufacturing Procedures outlined by the FDA cGMP. This recorder is safe and effective for the application for which it is intended and has been tested to confirm the safety and efficacy of the recorder. The RZ153+ is found to be **substantially equivalent** to the DR180II

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2002

Rozinn Electronics, Inc.
c/o Mr. Mark Rosoff
President
71-22 Myrtle Avenue
Glendale, NY 11385

Re: K022540
Trade Name: Cardio ID+ RZ153+
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: DSH
Dated: July 29, 2002
Received: August 1, 2002

Dear Mr. Rosoff:

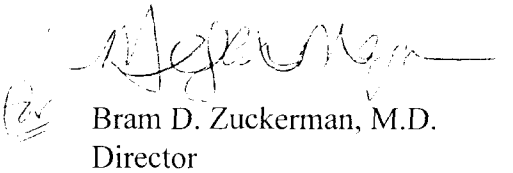
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(K) number (if known): K022540

Device Name: Cardio ID+ RZ153+

Indications for use: Detection of Arrhythmia. The Rozinn 153+ is indicated for use in continuous monitoring of Cardiac rhythm when intermittent arrhythmia are suspected due to patient symptoms such as palpitations, transient ischemic attacks, syncope, and the symptoms as determined by the physician. Efficacy of treatment using the 153+ is indicated for use to determine whether current pharmacological treatment (s) of known arrhythmia is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment. Pacemaker evaluation is also indicated for use to evaluate the function of implanted pacemakers to insure that the pacemaker is functioning within prescribed limits. This device is to be used only by the order of a physician

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022540